



May 11, 2007

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 07-06

Animal and Plant
Health Inspection
Service

Subject: Preparation and Testing of Experimental Biological Products that are
Derived from Biotechnology

Veterinary Services

Center for Veterinary
Biologics

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
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I. PURPOSE

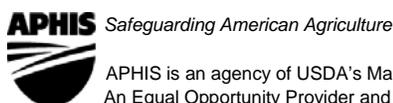
The purpose of this notice is to inform biologics firms of the expectations of the Center for Veterinary Biologics (CVB) regarding conditions for research and development of biotechnology-derived products.

II. BACKGROUND

Title 9, Code of Federal Regulations (9CFR), Part 103.1, indicates that preparation of experimental biological products must not result in contamination of licensed products. It further specifies that each request for permission to prepare an experimental biological product on licensed premises shall indicate the nature of the unlicensed product, designate facilities to be used, and specify precautions which will be taken to prevent contamination of licensed products.

In 1994, the National Institutes of Health published "Guidelines for Research Involving Recombinant DNA Molecules" (NIH Guidelines). Numerous amendments have been made since then. The NIH Guidelines provide for oversight by an Institutional Biosafety Committee (IBC), a group of diverse individuals knowledgeable about the NIH Guidelines and its ranking of the human health risks posed by specific pathogens. They also make physical containment recommendations for large-scale use of organisms containing recombinant DNA molecules. These recommendations, designated as Biosafety Level 1, 2, 3, or 4, refer to the degree of human health risk, not to animal health or environmental risk. Federal laboratories (including the CVB laboratory) as well as many academic and other non-Federal laboratories operate under these guidelines.

A comprehensive biosafety risk assessment also requires characterization of hazards to animal health. In 2004 the World Health Organization (WHO) established their classification of infective microorganisms using 4 risk groups for animal and human disease based on pathogenicity, modes of transmission, and host range of the organism.



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The National Environmental Policy Act (NEPA) was passed in 1969. It requires that environmental impact be evaluated prior to release of an agent. Where adverse environmental effects might be anticipated, alternative options or at least sufficient mitigation of the negative effects must be explored.

Deliberate release of any organism containing recombinant DNA into the environment is subject to review and approval by appropriate Federal agencies. Under normal husbandry and laboratory practices, injected veterinary biologics are not considered to be released into the environment, provided that the vaccine organism is not shed after vaccination. Any microbial agents that are shed are considered to be released into the environment.

III. POLICY

When making a request to the CVB for permission to prepare an experimental biological product on licensed premises, per 9CFR Part 103.1, firms should indicate the nature of the unlicensed product (including if it is biotechnology-derived), designate the facilities to be used, and specify precautions which will be taken to prevent contamination of licensed products. Food animals vaccinated with an experimental biotechnology-derived product cannot enter the human food chain unless a risk analysis is conducted and approved by the CVB. This is in addition to the usual pre-slaughter considerations regarding whether the adjuvant is approved for use in the species of animals vaccinated, the appropriate withdrawal time has been observed (per 9CFR Part 112.2(a)(8) and VS Memorandum 800.51), and animals are not diseased or unhealthy following the conclusion of a vaccination/challenge study.

The CVB strongly recommends that biologics firms working with experimental biotechnology-derived products comply with NEPA and provide appropriate containment to ensure low risk to human and animal health and to the environment. Research on recombinant organisms should be evaluated and approved by the firm's IBC or an equivalent body. The evaluation by an IBC or an equivalent body should be conducted for research facilities that are entirely separate and apart from production facilities of a licensed establishment, as well as for research facilities that are on the same premises as the production facilities.

Firms may wish to ship experimental biotechnology-derived products for testing in animals. Required documentation to request authorization to ship experimental product is described in 9CFR Part 103.3 and VS Memorandum 800.67. In addition, the firm proposing to ship the biological product should provide a description of the recombinant and its construction (including any vectors used) and documentation of evaluation and approval by the IBC or an equivalent body of the institution conducting the testing.

/s/Richard E. Hill, Jr.

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Director
Center for Veterinary Biologics